

111TH CONGRESS  
1ST SESSION

# H. R. 2824

To enhance the conduct and support of federally funded comparative effectiveness research relating to health care, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 11, 2009

Mrs. CHRISTENSEN (for herself, Mr. HERGER, and Mr. BOUSTANY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Armed Services, and Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To enhance the conduct and support of federally funded comparative effectiveness research relating to health care, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Doctor-Patient Rela-  
5       tionship and Research Protection Act”.

1 **SEC. 2. FEDERAL COORDINATING COUNCIL FOR COMPARA-**  
2 **TIVE EFFECTIVENESS RESEARCH.**

3 (a) **AUTHORITY.**—Paragraph (1) of section 804(c) of  
4 title VIII of division A of the American Recovery and Re-  
5 investment Act of 2009 (42 U.S.C. 299b–8(c)) is amended  
6 to read as follows:

7 “(1) notwithstanding the provisions under the  
8 heading ‘AGENCY FOR HEALTHCARE RESEARCH AND  
9 QUALITY’ of this title and any other provision of law,  
10 have full authority to direct and coordinate all Fed-  
11 eral funding of comparative effectiveness health care  
12 research, including such research conducted or sup-  
13 ported by the Departments of Health and Human  
14 Services, Veterans Affairs, and Defense; and”.

15 (b) **MEMBERSHIP.**—Subsection (d) of section 804 of  
16 title VIII of division A of the American Recovery and Re-  
17 investment Act of 2009 (42 U.S.C. 299b–8) is amended  
18 to read as follows:

19 “(d) **MEMBERSHIP.**—

20 “(1) **IN GENERAL.**—The members of the Coun-  
21 cil shall include one senior officer or employee from  
22 each of the following agencies:

23 “(A) The Agency for Healthcare Research  
24 and Quality.

25 “(B) The Secretary of Health and Human  
26 Services.

1           “(C) The Director of the National Insti-  
2           tutes of Health.

3           “(D) 20 members, 9 of whom are not full-  
4           time government employees, appointed by the  
5           Comptroller General of the United States as  
6           follows:

7                   “(i) 3 members representing patients  
8                   and health care consumers.

9                   “(ii) 3 members representing prac-  
10                  ticing physicians, including surgeons.

11                  “(iii) 3 members representing agen-  
12                  cies that administer public programs, as  
13                  follows:

14                           “(I) 1 member representing the  
15                           Centers for Medicare & Medicaid  
16                           Services who has experience in admin-  
17                           istering the program under title  
18                           XVIII of the Social Security Act.

19                           “(II) 1 member representing  
20                           agencies that administer State health  
21                           programs (who may represent the  
22                           Centers for Medicare & Medicaid  
23                           Services and have experience in ad-  
24                           ministering the program under title  
25                           XIX or the program under title XXI

1 of the Social Security Act or be a gov-  
2 ernor of a State).

3 “(III) 1 member representing  
4 agencies that administer other Fed-  
5 eral health programs (such as a  
6 health program of the Department of  
7 Defense Federal employees health  
8 benefits program under chapter 89 of  
9 title 5 of the United States Code, a  
10 health program of the Department of  
11 Veterans Affairs under chapter 17 of  
12 title 38 of such Code, or a medical  
13 care program of the Indian Health  
14 Service or of a tribal organization).

15 “(iv) 3 members representing private  
16 payers, of whom at least 1 member shall  
17 represent health insurance issuers and at  
18 least 1 member shall represent employers  
19 who self-insure employee benefits.

20 “(v) 3 members representing pharma-  
21 ceutical, device, and technology manufac-  
22 turers or developers.

23 “(vi) 1 member representing nonprofit  
24 organizations involved in health services re-  
25 search.

1 “(vii) 1 member representing organi-  
2 zations that focus on quality measurement  
3 and improvement or decision support.

4 “(viii) 1 member representing inde-  
5 pendent health services researchers.

6 “(ix) 1 member representing research  
7 in differences in treatment outcomes along  
8 the lines of racial and ethnic background,  
9 gender, and geography.

10 “(x) 1 member representing research  
11 in treating rural populations.

12 “(E) QUALIFICATIONS.—At least half of  
13 the members of the Council shall be physicians  
14 or other experts with clinical expertise.

15 “(2) CHAIRMAN; VICE CHAIRMAN.—The Sec-  
16 retary shall serve as Chairman of the Council and  
17 shall designate a member to serve as Vice Chair-  
18 man.”.

19 (c) RULES OF CONSTRUCTION.—Subsection (g) of  
20 section 804 of title VIII of division A of the American  
21 Recovery and Reinvestment Act of 2009 (42 U.S.C. 299b–  
22 8) is amended to read as follows:

23 “(g) RULES OF CONSTRUCTION.—

24 “(1) COVERAGE.—Nothing in this section shall  
25 be construed—

1 “(A) to permit the Council to mandate or  
2 recommend coverage, reimbursement, or other  
3 policies for any public or private payer; or

4 “(B) as preventing the Secretary of Health  
5 and Human Services from covering the routine  
6 costs of clinical care received by an individual  
7 entitled to, or enrolled for, benefits under title  
8 XVIII, XIX, or XXI of the Social Security Act  
9 in the case where such individual is partici-  
10 pating in a clinical trial and such costs would  
11 otherwise be covered under such title with re-  
12 spect to the beneficiary.

13 “(2) REPORTS AND FINDING.—No report sub-  
14 mitted under this section or research findings dis-  
15 seminated by the Council shall be construed as man-  
16 dates, guidelines, or recommendations for payment,  
17 coverage, or treatment.”.

18 (d) TRANSPARENCY, CREDIBILITY, AND ACCESS.—  
19 Section 804 of title VIII of division A of the American  
20 Recovery and Reinvestment Act of 2009 (42 U.S.C. 299b–  
21 8) is amended by adding at the end the following:

22 “(h) TRANSPARENCY, CREDIBILITY, AND ACCESS.—  
23 The Council shall establish procedures to ensure that the  
24 following requirements for ensuring transparency, credi-  
25 bility, and access are met:

1 “(1) PUBLIC COMMENT PERIOD.—

2 “(A) COMMENT PRIOR TO OBLIGATION OF  
3 FUNDS FOR RESEARCH.—Before any Federal  
4 funds may be obligated to conduct or support  
5 comparative effectiveness research, the Council  
6 shall provide for a period of not less than 30  
7 days for the public to comment on the research  
8 proposal.

9 “(B) COMMENT AFTER RESEARCH RE-  
10 SULTS PUBLISHED.—After the publication of  
11 the results of research described in subpara-  
12 graph (A), the Council shall provide for a pe-  
13 riod of 60 days for the public to comment on  
14 such results.

15 “(C) TRANSMISSION OF PUBLIC COM-  
16 MENTS.—The Council shall ensure the trans-  
17 mission of public comments submitted under  
18 subparagraph (A) to the entity conducting the  
19 research with respect to which the individual  
20 study design is being finalized.

21 “(2) ADDITIONAL FORUMS.—The Council shall,  
22 in addition to the public comment period described  
23 in paragraph (1), support forums to increase public  
24 awareness and obtain and incorporate public feed-

1 back through media (such as an Internet website) on  
2 the following:

3 “(A) The identification of comparative ef-  
4 fectiveness research priorities.

5 “(B) Comparative effectiveness research  
6 findings.

7 “(C) Any other duties, activities, or proc-  
8 esses the Council determines appropriate.

9 “(3) PUBLIC AVAILABILITY.—The Council shall  
10 make available to the public and disclose through  
11 the official public Internet website of the Council,  
12 and through other forums and media the Council de-  
13 termines appropriate, the following:

14 “(A) The process and methods for the con-  
15 duct of comparative effectiveness research pur-  
16 suant to this section, including—

17 “(i) the identity of the entity con-  
18 ducting any such research;

19 “(ii) any links the entity has to indus-  
20 try (including such links that are not di-  
21 rectly tied to the particular research);

22 “(iii) draft study designs (including  
23 research questions and the finalized study  
24 design, together with public comments on



1           such study design and responses to such  
2           comments);

3           “(iv) research protocols (including  
4           measures taken, methods of research,  
5           methods of analysis, research results, and  
6           such other information as the Council de-  
7           termines appropriate);

8           “(v) the identity of investigators con-  
9           ducting such research and any conflicts of  
10          interest of such investigators; and

11          “(vi) any progress reports the Council  
12          determines appropriate.

13          “(B) Public comments submitted during  
14          each public comment period under paragraph  
15          (1)(A).

16          “(C) Bylaws, processes, and proceedings of  
17          the Council, to the extent practicable and as the  
18          Council determines appropriate.

19          “(D) Not later than 60 days after receipt  
20          by the Council of a relevant report or compara-  
21          tive effectiveness research finding, appropriate  
22          information contained in such report or finding.

23          “(4) CONFLICTS OF INTEREST.—

24          “(A) IN GENERAL.—The Council shall—

1 “(i) in appointing members to an ad-  
2 visory panel, and in selecting individuals to  
3 contribute to any peer-review process and  
4 for employment as executive staff of the  
5 Council, take into consideration any con-  
6 flicts of interest of potential appointees,  
7 participants, and staff; and

8 “(ii) include a description of any such  
9 conflicts of interest and conflicts of inter-  
10 est of Council members in an annual re-  
11 port to the Congress, except that, in the  
12 case of individuals contributing to any  
13 such peer review process, such description  
14 shall be in a manner such that those indi-  
15 viduals cannot be identified with a par-  
16 ticular research project.

17 “(B) DEFINITION.—In this subsection, the  
18 term ‘conflict of interest’ means associations,  
19 including financial and personal, that may be  
20 reasonably assumed to have the potential to  
21 bias an individual’s decisions in matters related  
22 to the Council or the conduct of the compara-  
23 tive effectiveness research.”.

1 **SEC. 3. APPLICATION OF FEDERALLY FUNDED CLINICAL**  
2 **COMPARATIVE EFFECTIVENESS RESEARCH.**

3 (a) LIMITATION ON CMS.—The Administrator of the  
4 Centers for Medicare & Medicaid Services may not use  
5 federally funded clinical comparative effectiveness re-  
6 search data to make coverage determinations under title  
7 XVIII of the Social Security Act for medical treatments,  
8 services, and items on the basis of cost.

9 (b) REQUIREMENT FOR IMPLEMENTATION.—Feder-  
10 ally funded clinical comparative effectiveness research and  
11 related evaluation and communication activities shall re-  
12 flect the principle that clinicians and patients should have  
13 the best available evidence upon which to make choices  
14 in health care items and services, in providers, and in  
15 health care delivery systems, recognizing that patient sub-  
16 populations and patient and physician preferences may  
17 vary.

18 (c) APPEALS OF CERTAIN MEDICARE COVERAGE DE-  
19 TERMINATIONS.—In the case of a national or local cov-  
20 erage determination under title XVIII of the Social Secu-  
21 rity Act that has been made utilizing federally funded  
22 comparative effectiveness research, an individual entitled  
23 to benefits under such title shall—

24 (1) be an eligible requester under section  
25 1869(h)(1)(B) of such Act in relation;

1           (2) have expedited access (as specified by the  
2       Secretary) to coverage determinations, redetermina-  
3       tions, and appeals relating to such determinations;  
4       and

5           (3) have full access to all administrative or judi-  
6       cial review under section 1869 of such Act with re-  
7       spect to such determinations.

8       (d) RULE OF CONSTRUCTION.—Nothing in this Act  
9       or the amendments made by this Act shall be construed  
10      to require coverage of any drug, biological product, device,  
11      or treatment that has been determined by the Food and  
12      Drug Administration to be unsafe.

13      (e) DISAGGREGATION OF RESEARCH RESULTS.—No  
14      Federal funds may be made available to any person for  
15      any federally funded clinical comparative effectiveness re-  
16      search, unless the person agrees to ensure that, whenever  
17      possible, the methodology and research protocols will in-  
18      clude variables that not only measure, but can be  
19      disaggregated to analyze and identify, any differences  
20      along the lines of racial and ethnic background, gender,  
21      and geography that may exist among and within patient  
22      subpopulations.

23      (f) DEFINITIONS.—In this section:

1           (1) The term “federally funded clinical com-  
2       parative effectiveness research” means research  
3       that—

4           (A) evaluates and compares the clinical ef-  
5       fectiveness, risks, and benefits of 2 or more  
6       medical treatments, services, and items; and

7           (B) is conducted or supported in accord-  
8       ance with provisions of title VIII of division A  
9       of the American Recovery and Reinvestment  
10      Act of 2009 or with the use of other Federal  
11      funds.

12          (2) The term “medical treatments, services, and  
13      items” means health care interventions, protocols for  
14      treatment, procedures, medical devices, diagnostic  
15      tools, pharmaceuticals (including drugs and  
16      biologicals), and any other processes or items being  
17      used in the treatment and diagnosis of, or preven-  
18      tion of illness or injury in, patients.

19          (3) The term “patient subpopulations” means  
20      populations of patients of different racial and ethnic  
21      backgrounds, genders, and geographic locations.

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